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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,445	09/19/2003	Robert Rabiner	18554-001001	7310
26161	7590	01/18/2007	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			SONNETT, KATHLEEN C	
		ART UNIT		PAPER NUMBER
				3731
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	01/18/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)
	10/665,445	RABINER ET AL.
	Examiner	Art Unit
	Kathleen Sonnett	3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 December 2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-44 is/are pending in the application.
 4a) Of the above claim(s) 10-44 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-9 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 19 September 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date
9/19/03, 1/2/04, 9/27/04, 9/19/05, 9/27/06, 12/12/06.

DETAILED ACTION

Information Disclosure Statement

1. Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. See MPEP 609.05(b). Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. **Claims 1 and 5 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 and 2, respectively, of U.S. Patent No. 6,524,251.**
Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the same invention; the application claims are merely broader in

scope than the claims of U.S. 6,524,251. The patented claims therefore anticipate the application claims.

3. **Claims 1 and 5** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24 and 25, respectively, of copending Application No. 10,373,134 (as filed on 10/16/2006 in an amendment after non-final action). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the same invention; the application claims are merely broader in scope than the claims of copending Application No. 10,373,134. The claims 24 and 25 of copending Application No. 10,373,134 therefore anticipate claims 1 and 5 of the instant application.

4. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1, 3, 4, 5, and 9** are rejected under 35 U.S.C. 102(b) as being anticipated by DonMicheal et al. (U.S. 4,870,9523). DonMicheal et al. discloses an ultrasonic probe for removing an occlusion in a blood vessel comprising a first terminus at a proximal end of the ultrasonic probe, a second terminus at a distal end of the ultrasonic probe terminating in a probe tip, and a longitudinal axis between the two termini wherein the probe vibrates in a transverse direction generating a plurality of nodes and anti-nodes of cavitation energy along the

longitudinal axis of the ultrasonic probe to produce an occlusion destroying effect along at least a portion of the longitudinal axis of the ultrasonic probe (col. 5 ll. 22-25; 48-52; 56-61).

DonMicheal et al. discloses that the length of the probe may be a whole number multiple of one-half the wavelength of the ultrasonic frequency with the probe tip being at an anti-node (Note: DonMicheal et al. defines an anti-node as a point of peak motion whereas applicant defines a node as a point of peak motion). This can result in a plurality of nodes and anti-nodes.

7. Regarding claim 3, the diameter of the probe is approximately uniform from the first terminus to the second terminus. Although the tip is enlarged, the rest of the probe is uniform. As seen in fig. 3, the diameter of the enlarged tip (second terminus) does not appear to be much larger than the diameter of the rest of the probe. The examiner is considering this approximately uniform since, for most of the distance between the first and second termini, the diameter is uniform.

8. Regarding claim 4, see col. 6 ll. 65-col. 7 ll. 2.

9. Regarding claim 5, sheath (8) surrounds at least a portion of the probe (see fig. 3).

10. Regarding claim 9, the ultrasonic probe vibrates in a transverse vibration. The transverse vibration causes a retrograde flow of debris away from the probe tip.

11. **Claims 1, 3, and 5** are rejected under 35 U.S.C. 102(b) as being anticipated by DeCastro (U.S. 5,830,127). DeCastro discloses an ultrasonic probe comprising a first terminus at a proximal end of the ultrasonic probe and a second terminus at a distal end of the ultrasonic probe, a longitudinal axis between the termini wherein the probe vibrates in a transverse direction generating a plurality of nodes and antinodes of cavitation energy along the longitudinal axis of the ultrasonic probe to produce an occlusion destroying effect along the longitudinal axis of the probe (see fig. 2 and fig. 6).

Art Unit: 3731

12. Regarding claim 5, when the probe is inserted into an endoscope for cleaning the instrument, the endoscope can be considered a sheath that surrounds at least a portion of the longitudinal axis of the probe.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. **Claim 2** is rejected under 35 U.S.C. 103(a) as being unpatentable over DonMicheal et al. in view of Weng et al. (U.S. 5,269,297). DonMicheal et al. discloses the invention substantially as stated above but fails to disclose that the diameter of the probe decreases at defined intervals from the first to the second terminus.

15. However, Wang et al. discloses providing tapered sections (16a) along the probe which form defined intervals where the diameter of the probe decreases from the first to the second terminus (see fig. 1A). These sections serve to increase the displacement produced in response to a given level of input ultrasonic energy (see fig. 1b and col. 7 ll. 5-22). Wang et al. further discloses that having tapered sections that fall at defined intervals instead of having a single continuously tapered probe provides better attenuation characteristics (col. 8 ll. 1-6). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of DonMicheal et al. to decrease the diameter of the ultrasonic probe at defined intervals from the first to the second terminus as made obvious Wang et al. in order to increase the displacement of the probe while still providing favorable attenuation characteristics.

16. **Claim 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over DonMicheal et al. in view of Boyd (U.S. 3,433,226). DonMicheal et al. discloses the invention substantially as stated above but fails to disclose that the occlusion is reduced to a micron-sized particle.

17. However, Boyd discloses that it is old and well known in the art to use an ultrasonic probe that has a plurality of nodes and antinodes (see fig. 1 which shows length of probe sections as related to wavelength) to reduce an occlusion to micron-sized particles (col. 2 ll. 37-41). These small fragments can easily be flushed away. Therefore, it would have been obvious to one of ordinary skill in the art to modify DonMicheal et al. to use a frequency which causes an occlusion to be broken into micron-sized particles as made obvious by Boyd so that the fragments are of a size that allows them to easily be flushed away.

18. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over DonMicheal et al. in view of Parisi (U.S. 4,169,984). DonMicheal discloses the invention substantially as stated above, but fails to disclose one or more irrigation passages along at least a portion of the longitudinal axis of the ultrasonic probe.

19. However, Parisi discloses that it is old and well known to make a probe hollow such that an irrigation passage is provided along the longitudinal axis of the probe. This channel allows irrigating fluid to flow from the probe such that the fluid removes the broken particles from the surface of the area being ultrasonically pulverized (see col. 3 ll. 44-46). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of DonMicheal et al. to include an irrigation passage along the longitudinal axis of the ultrasonic probe as made obvious by Parisi in order to be able to flush the broken up pieces of tissue away from the working surface.

20. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over DonMicheal et al. in view of Acosta et al. (U.S. 5,772,627). DonMicheal et al. discloses the invention

Art Unit: 3731

substantially as stated above but fails to disclose an aspiration channel along at least a portion of the longitudinal axis of the ultrasonic probe.

21. However, Acosta et al. discloses that it is old and well known in the art to provide a hollow ultrasonic probe such that the probe defines an aspiration channel. This aspiration channel allows tissue broken down by the tip to be easily evacuated (see col. 2 ll. 47-52). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of DonMicheal et al. to make the ultrasonic probe hollow such that it defines an aspiration channel as made obvious by Acosta et al. in order to be able to evacuate tissue that has been broken down by the tip.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: U.S. Patent 6,652,547 and U.S. Application Publication 2004/0158150 both to Rabiner et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 12/14/2006



GLENN K. DAWSON
PRIMARY EXAMINER